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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,861	02/07/2002	Kevin M. Slawin	675.002US1	1421

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EXAMINER	
HOLLERAN, ANNE L	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 03/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/071,861	SLAWIN ET AL.	
	Examiner	Art Unit	
	Anne Holleran	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-35 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-35 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Prior to setting forth the restriction requirement, it is noted that the claims recite improper Markush Groups. M.P.E.P. 803.02 states that: Since the decisions in *In re Weber*, 580 F.2d 455, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 580 F.2d 461,198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, *unless the subject matter in a claim lacks unit of invention* [emphasis added], *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility. In the instant case, the products used in the claimed methods are separate and distinct polypeptide products that differ in structure and origin to such an extent that non-coextensive searches are required, and that the polypeptide products are considered to lack a substantial structural feature disclosed as being essential to the disclosed utility. As such, the methods using agents that bind to the structurally different polypeptide products have been restricted each from the other.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, 15-20, 22-25 (to the extent the claims read on methods of detecting TGF-beta1), drawn to methods for determining the risk of progression of a

prostate cancer patient after therapy comprising detecting the level of complex formation between an agent and TGF-beta1, classified in class 435, subclass 7.1.

II. Claims 1-13, 15-20, 22-25 (to the extent the claims read on methods of detecting IGFBP-2), drawn to drawn to methods for determining the risk of progression of a prostate cancer patient after therapy comprising detecting the level of complex formation between an agent and IGFBP-2, classified in class 435, subclass 7.1.

III. Claims 1-13, 15-20, 22-25 (to the extent the claims read on methods of detecting IGFBP-3) drawn to methods for determining the risk of progression of a prostate cancer patient after therapy comprising detecting the level of complex formation between an agent and IGFBP-3, classified in class 435, subclass 7.1.

IV. Claims 2, 3, 5-19, 21-25 (to the extent the claims read on methods of detecting IL-6 or IL-6sR), drawn to drawn to methods for determining the risk of progression of a prostate cancer patient after therapy comprising detecting the level of complex formation between an agent and IL-6 or IL-6sR, classified in class 435, subclass 7.1.

V. Claims 28-35, drawn to an apparatus for analyzing data and method of using the apparatus.

3. The inventions are distinct, each from the other, for the following reasons:

Inventions I-IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different

inventions, each of the methods uses agents that bind to separate and distinct polypeptide products do not share structural features. The polypeptide sequence of TGF-beta1 is separate and distinct from the polypeptide sequence of IGFBP-2, IGFBP-3, and either of IL-6 or IL-6sR. Therefore, the methods require the use of separate and distinct agents that bind to TGF-beta1, IGFBP-2, IGFBP-3, and either of IL-6 or IL-6sR.

Furthermore, it would impose an undue burden on the examiner to search and examine invention groups I-IV together, because the searches are not co-extensive. The search for the relationship between a cancer and levels of protein such as TGF-beta1 is not coextensive with the search that is required for the examination of methods having to do with the relationship between a cancer and levels of a protein such as any of IGFB-2, IGFBP-3 or either of IL-6 or IL-6sR.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for any of Groups II-IV, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group III or IV restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group IV, restriction for examination purposes as indicated is proper.

Invention V is distinct from any of inventions I-IV because invention V is drawn to an apparatus and a method of using the apparatus, where the apparatus appears to be a data analyzing apparatus. The recitation that the input test information is that derived from any of the methods of inventions I-IV appears to be an intended use limitation. Thus, invention V appears to be drawn to an apparatus and method of using an apparatus that may be used for almost any type of data. Therefore, it would be an undue burden on the examiner to search and examine invention V with any of inventions I-IV because the search for a generic apparatus that may be useful for analyzing any type of input data is not coextensive with the search required for any of inventions I-IV, which are inventions having to do with the relationship of cancer and the levels of TGF-beta1, IGFBP-2, IGFBP-3, and either of IL-6 or IL-6sR.

Because these inventions are distinct for the reasons given above and the search required for Group V is not required for Groups I-IV, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (571) 272-0833. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew, can be reached at (571) 272-0787.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 571-1600.

Anne L. Holleran
Patent Examiner
March 21, 2005

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER